

**Remarks/Arguments:**

**Information Disclosure Statement**

Applicants filed an Information Disclosure Statement (IDS) on June 14, 2004, and a Supplemental IDS on November 2, 2004, submitting prior art references for the Examiner's review. A review of the USPTO public database indicates that these IDS's are in the file and were available to the Examiner at the time of examination. Applicants respectfully request confirmation that the Examiner considered the cited references prior to issuing the present Office Action and respectfully request receiving indication of same in the next Office Action.

**Rejections under 35 U.S.C. §102**

In the Office Action, the Examiner rejected claims 16 and 22-26 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,967,744 to Chua ("Chua"). In the Office Action, the Examiner stated that Chua discloses a system for delivering humidified gas to a patient, with a supply unit 10 configured to deliver humidified gas and a delivery tube assembly 30 having a delivery tube with a proximal end (at 60) and a distal end (at 52). The Examiner stated that the delivery tube has a fitting 60 positioned at the proximal end that is adapted for connection to the supply unit, with the delivery tube assembly being configured (42) to transfer heat to the humidified gas. Applicants respectfully traverse this rejection as it applies to amended claim 16.

Claim 16, as amended, recites, *inter alia*, a system for delivering humidified gas to a patient. The system comprises a supply unit configured to deliver humidified gas and a delivery tube assembly having a delivery tube with a proximal end and a distal end. The delivery tube assembly also has a fitting positioned at the proximal end of the delivery tube and releasably coupled to said supply unit. The delivery tube assembly is configured to transfer heat to the humidified gas received from said supply unit. A nasal cannula is releasably coupled to the distal end of the delivery tube to receive humidified gas from the delivery tube of the delivery tube assembly. Emphasis added.

In order to anticipate a claim under 35 U.S.C. §102, the reference must teach every element of the claim. M.P.E.P. §2131. Furthermore, "the identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and M.P.E.P. §2131. Chua discloses a breathing device that includes a patient connector 50 that is inserted into a patient's mouth for

the patient to inhale the breathing gas generated by Chua's device. Additionally, Chua discloses only that the patient connector 50 is connected to the co-axial tube 30 by a swivel connection. Chua fails to disclose or suggest whether the patient connector 50 is releasably connected to the tube 30.

Chua also fails to disclose a supply unit configured to deliver humidified gas with a supply tube having a proximal fitting releasably coupled to the supply unit. The claimed releasable feature of the delivery tube with respect to the supply unit allows the delivery tube to be easily replaced should it become damaged or otherwise unusable.

Additionally, Chua fails to disclose or suggest a nasal cannula that is releasably connected to the distal end of the delivery tube. Chua only discloses a mouthpiece that provides air to the patient's mouth (See, e.g., column 3, lines 11-12; Fig. 2).

The claimed nasal cannula has several important advantages as compared to the Chua mouthpiece. First, the claimed nasal cannula allows a patient to breath the breathing gas that is being administered by the system, yet still be able to perform other functions with his/her mouth, such as speak and/or eat. Chua's device does not provide for such normal physical functions to be performed while using his device.

Further, the claimed nasal cannula allows breathing gas to be administered to the patient at body temperature pressure saturated (BTPS). Also, a nasal cannula can fill the nasal pharynx, thus providing fresh breathing gas to the patient. Further, the claimed nasal cannula eliminates the problem of rain-out that may be experienced with Chua's device.

Additionally, the claimed nasal cannula is releasable from the delivery tube. This feature allows the nasal cannula to be removed and replaced in the event that the nasal cannula becomes damaged or otherwise unusable. Chua, on the other hand, teaches a swivel connection (see, e.g., column 3, lines 6-11).

For at least the reasons cited above, Applicants respectfully submit that claim 16 is patentable over the cited prior art. Applicants respectfully request reconsideration and allowance of claim 16.

Claims 22-26 all depend, either directly or indirectly, from claim 16, and Applicants respectfully submit that claims 22-26 are patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 16.

**Rejections under 35 U.S.C. §103**

The Examiner also rejected claims 17, 18, and 27-30 under 35 U.S.C. 103(a) as being unpatentable over Chua in view of U.S. Patent No. 5,349,946 to McComb ("McComb"). Claims 17, 18, and 27-29 all depend, directly or indirectly, from amended claim 16, and Applicants respectfully submit that claims 17, 18, and 27-29 are patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 16, and because the McComb reference does not overcome the deficiencies of Chua as set forth above. Applicants therefore respectfully request reconsideration and allowance of claims 17, 18, and 27-29.

Regarding independent claim 30, the Examiner stated that claim 30 is essentially equivalent in scope to claim 17. Chua is described above. McComb discloses a breathing device 10 in which a mouthpiece is inserted into the patient's mouth to administer breathing gas to the patient. See Fig. 1. Neither Chua nor McComb disclose or suggest using the nasal cannula as recited in claim 30.

The benefits of using the nasal cannula as opposed to supplying humidified air into the patient's mouth are recited above with respect to claim 16.

Applicants respectfully submit that the combination of Chua and McComb fails to teach or disclose the claimed method delivering humidified gas through a nasal cannula. Applicants therefore respectfully submit that the combination of Chua and McComb is improper and respectfully request reconsideration and allowance of claim 30.

Also, the Examiner rejected claims 19-21 and 32 under 35 U.S.C. 103(a) as being unpatentable over Chua in view of U.S. Patent No. 5,890,490 to Aylsworth ("Aylsworth"). Claim 19 has been cancelled, rendering the rejection of claim 19 moot. Claims 20 and 21 each depend from amended claim 16, and Applicants respectfully submit that claims 20 and 21 are patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 16, and because the Aylsworth reference does not overcome the deficiencies of Chua as set forth above.

Independent claim 32, as amended, recites, *inter alia*, a method for delivering humidified gas to a patient. The method comprises the steps of releasably connecting a fitting of a proximal end of a delivery tube to a supply unit; releasably coupling a nasal cannula to a distal end of the delivery tube; and delivering humidified gas from the supply unit, through the delivery tube, and into the nasal cannula for delivery to the patient. Emphasis added.

Chua is described above. Aylsworth discloses a breathing gas delivery device that includes a monitoring system that connects a nasal cannula 11 to a gas source 3. Aylsworth fails to disclose or suggest whether the nasal cannula is releasably coupled to a supply tube. In fact, Aylsworth fails to disclose whether the nasal cannula is connected to a supply tube at all. Fig. 1 shows that the nasal cannula 11 is connected directly to a monitoring system 1 at outlet port 9.

Applicants respectfully submit that the combination of Chua and Aylsworth fails to teach or disclose the claimed method of releasably connecting a fitting of a proximal end of a delivery tube to a supply unit and releasably coupling a nasal cannula to a distal end of the delivery tube. Applicants respectfully submit that the combination of Chua and Aylsworth is improper and respectfully request reconsideration and allowance of claim 32.

Further, the Examiner rejected independent claims 31 and 33 under 35 U.S.C. 103(a) as being unpatentable over Chua in view of both McComb and Aylsworth. Regarding claim 31, the Examiner stated that the differences between Chua and claim 31 are the delivery of humidified gas at a flow rate of between about 1 and 8 liters per minute and a nasal cannula configured to be coupled to receive the humidified gas from the distal end of the delivery tube assembly. The Examiner further states that McComb satisfies the flow rate teaching and that Aylsworth satisfies the teaching of connecting the nasal cannula to the delivery tube assembly.

Regarding claim 31, Applicants respectfully submit that there is no incentive to combine the references. Chua requires a breathing tube 50 that is inserted into the patient's mouth in order to provide the inhalation breathing gases and to expel the expiry gases. There is no incentive in Chua to substitute his mouth-inserted breathing tube 50 with a nasal cannula as recited in claim 31.

Further, Applicants respectfully submit that a combination of Chua with Aylsworth as suggested by the Examiner to achieve the method recited in claim 31 is improper. Chua

discloses a co-axial breathing tube 30 that utilizes an inner tube 40 to provide breathing gas for inhalation by the patient and an external expiry tube 32 for taking expired gases away from the patient. Any suggestion to modify Chua with a nasal cannula of Aylsworth is improper, because such a combination would render Chua's invention unworkable. Exhaust gases exhaled by the patient would not get into Chua's expiry tube, rendering Chua unworkable, for its intended purpose.

For at least these reasons, Applicants respectfully submit that the combination as suggested by the Examiner is improper, and request that the rejection of claim 31 be withdrawn.

Regarding claim 33, the Examiner stated that the claim is essentially equivalent in scope to claim 31. Applicants therefore repeat the arguments set forth above with respect to claim 31 and submit that, for at least these reasons, the combination as suggested by the Examiner is improper. Applicants therefore respectfully request that the rejection of claim 33 be withdrawn.

### **Conclusion**

In light of the amendments to claims 16 and 32, and the arguments set forth above, Applicants respectfully submit that claims 16-18 and 20-33 are in condition for allowance. Prompt reconsideration and allowance of same is respectfully requested.

Respectfully submitted,



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